Exploring Digital and Mobile Health Approaches in Patient-Oriented Research: Pearls & Pitfalls

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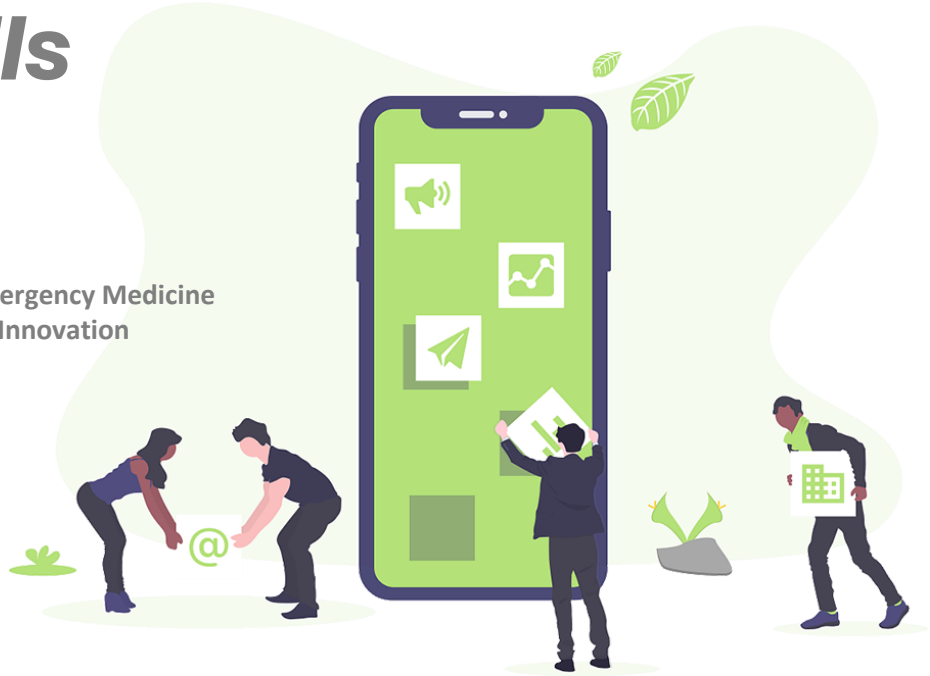

Disclosures

- Funding: AHRQ/PCORI, NIDA, NIMH, & the FDA
- Career: EM physician in an urban, academic environment
- Personal:
  - Deep interest in connecting with individuals
  - Believe in rapid-cycle innovation and studies
  - Father of two boys (5 and 2 yo) in the pandemic

Objectives:

Briefly frame the concepts of digital and mobile health

Personal examples of digital applications and methods in patient-oriented research

Successes, Failures, and the Future

Learning Health Systems, Personal Experiences & Research

- Academic, urban emergency medicine
- Health services researcher
- Patient-centered outcomes and engagement
- Rapidly inform clinical practice

Digital and Mobile Health

- Definition and landscape
- Rapidly evolving
- Integration across health platforms varies
- Disparities exist in access

Study:

RCT using wearable devices and digital participant engagement/data collection

Motivating and increasing physical activity remains important and challenging.

JAMA Network | Open

Original Investigation | Nutrition, Obesity, and Exercise

Effect of Gamification With and Without Financial Incentives to Increase Physical Activity Among Veterans Classified as Having Obesity or Overweight
A Randomized Clinical Trial

Anish K. Agarwal, MD, MPH, MS; Kimberly J. Waddell, PhD; Dylan S. Small, PhD; Chalanda Evans, BS; Tory O. Harrington, MHCI; Rachel Djaraher, BS, RD; Ai Leen Oon, BA; Mitesh S. Patel, MD, MBA

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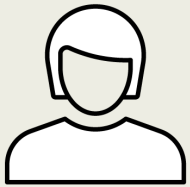
POPULATION

109 Men, 71 Women



Adult veterans with a body mass index ≥25 and access to a smartphone or tablet

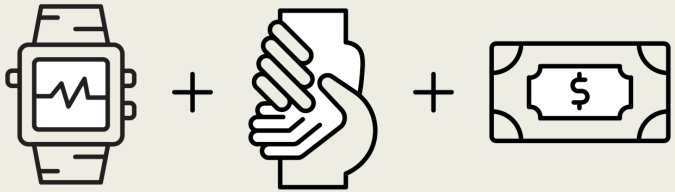
Mean (SD) age, 56.5 (12.9) y

SETTINGS / LOCATIONS

VA Medical Center, Philadelphia, PA

INTERVENTION

180 Participants randomized



60 Control
Use of wearable step-counting device, with no step goal game or support partner engagement

60 Gamification with social support
Wearable device + 12-wk automated game with points, levels, and a social support tracking mean step count

60 Loss-framed financial incentive
Gamification with social support + $120 payment, with $10 deducted weekly if step goals were not met

PRIMARY OUTCOME

Change in mean daily step count from the 2-wk baseline period to weeks 5-12 of the 12-wk intervention period, as measured by a wearable activity tracking device

Trial Design and Approach

Conduct a three arm RCT remotely using digital methods required key steps at enrollment, intervention, and follow-up.

Methods

Design

RCT testing gamification with social support +/- loss-framed financial incentive

Enrollment

Mailed letter of interest with follow up phone call to obtain informed consent and then sent a wearable device

Data Collection

Step count data from wearable device

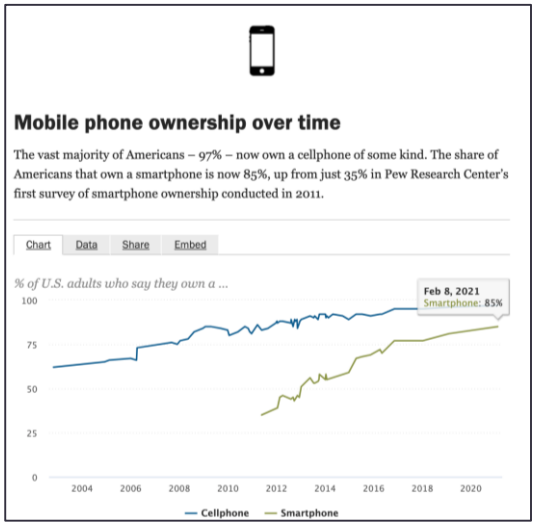
+

Text message based interaction

Key Takeaways

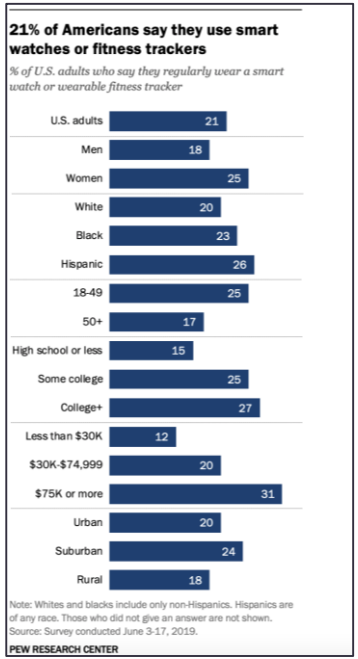
Design

Requires daily access to a
smartphone or tablet



Enrollment

Wearable devices

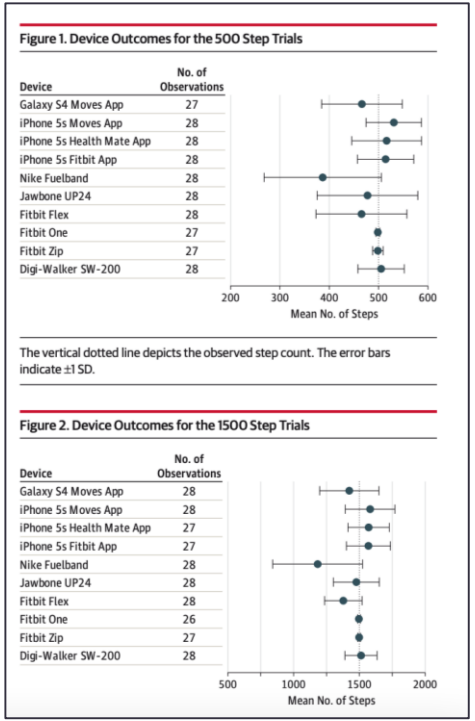


Research Letter
February 10, 2015

Accuracy of Smartphone Applications and Wearable Devices for Tracking Physical Activity Data

Meredith A. Case, BA[1]; Holland A. Burwick[2]; Kevin G. Volpp, MD, PhD[3]; et al
Author Affiliations | Article Information

JAMA. 2015;313(6):625-626. doi:10.1001/jama.2014.17841



Remote Engagement & Data Collection

Text Messaging and Data Integration

- Way To Health (@Penn), other vendors exist

Opportunities to fold in behavioral economics

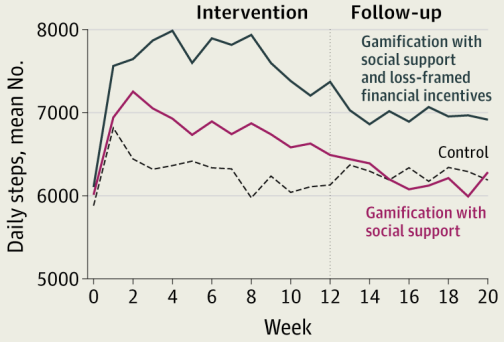
- Interaction/Competition with others (social support)
- Automated and dynamic notifications (gamification)
- Study logistics – reminders, payment, or follow up

Study Results & Lessons

- Remote enrollment
- Digital engagement
- Data integration

FINDINGS

Compared with control, veterans in the gamification with financial incentive group had a significant increase in mean daily step count but those in the gamification without financial incentive group did not



Mean adjusted difference in change in daily step count from baseline vs control:

Gamification with social support:
433 Steps (95% CI, −337 to 1203 steps); *P* =.81

Loss-framed financial incentives:
1224 Steps (95% CI, 451 to 1996 steps); *P* =.005

Study #2:

LHS research using prospective, simple text messaging at scale in post-operative patients

Acute Opioid Prescribing and the Opioid Epidemic

2nd most common type of illicit drug use
the ‘nonmedical’ use of prescription opioids e.g. diverted tablets

70% of individuals with OUD
used ‘left over’ tablets from friends or family

Up to 80%
of prescription opioid tablets are unused following surgery

A need to ‘Right-Size’

Higher Initial Prescriptions Linked with Family Member Overdose

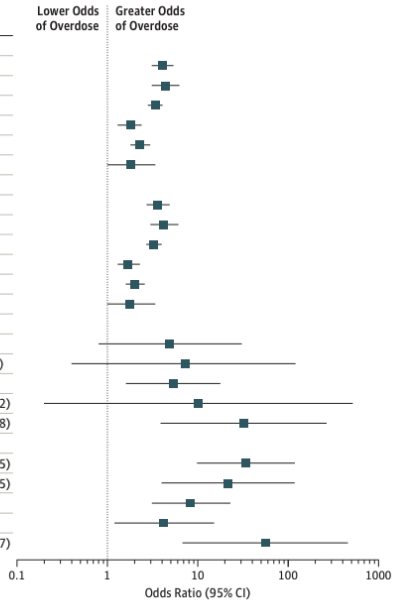
(Khan, JAMA IM 2019)

Acute Prescriptions Associated with Long Term Use

(Meisel, Annals of EM 2019)

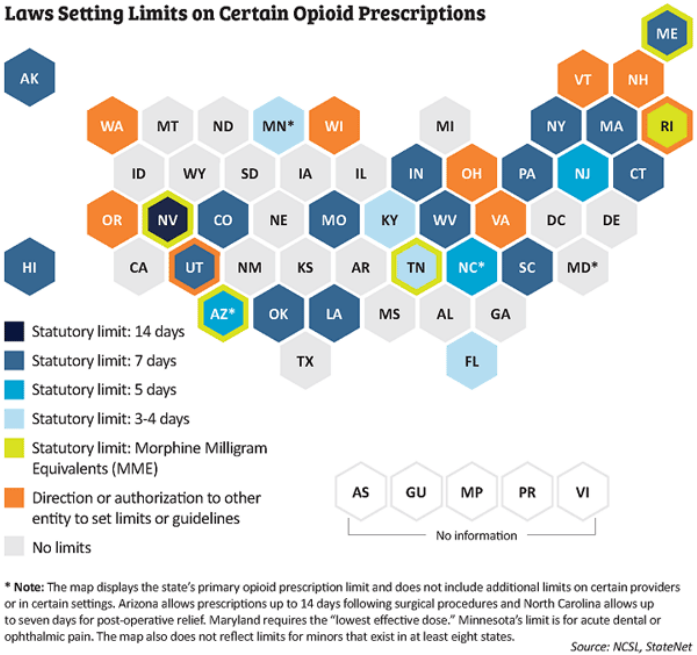
Figure 2. Odds Ratios for Overdose by Size of Opioid Prescription to Family Member

Exposure Measurements Age Group, y	Affected Individuals, No.	Odds Ratio (95% CI)
Binary		
0-6	177	4.08 (3.07-5.41)
7-12	177	4.38 (3.07-6.26)
13-18	392	3.38 (2.78-4.11)
19-34	121	1.78 (1.33-2.38)
35-59	154	2.28 (1.77-2.96)
≥60	27	1.80 (0.96-3.37)
0-<50 MME/d		
0-6	157	3.64 (2.72-4.86)
7-12	171	4.24 (2.96-6.08)
13-18	375	3.27 (2.68-3.99)
19-34	115	1.71 (1.27-2.31)
35-59	136	2.02 (1.55-2.64)
≥60	26	1.79 (0.95-3.35)
50-<90 MME/d		
0-6	2	4.94 (0.80-30.56)
7-12	1	7.22 (0.43-121.97)
13-18	7	5.37 (1.62-17.83)
19-34	1	10.10 (0.20-524.32)
35-59	7	32.39 (3.92-267.78)
≥90 MME/d		
0-6	18	34.22 (9.77-119.85)
7-12	5	21.71 (3.97-118.85)
13-18	10	8.38 (3.06-22.97)
19-34	5	4.18 (1.16-15.10)
35-59	11	56.25 (6.84-462.47)



The reference group for all categories is individuals with no opioids dispensed to family members. The odds ratios of overdose and 95% CIs were not reported for individuals aged 60 years and older in the categories of opioid dispensing to family members of 50 to less than 90 morphine milligram equivalents (MMEs) and 90 or more MMEs per day because of unstable estimates.

Policy & Practice



Opportunity:

Gather **patient-reported data** to inform providers and generate procedure, or injury, specific guidelines for acute opioid prescribing

Need for a novel approach

Patient-Reported

Pain Score

Ability to Mange Pain

Pain Medication Use

Non-opioid Analgesia

Opioid Consumption

Scalable

Accessible

Cross-cutting

Adaptable

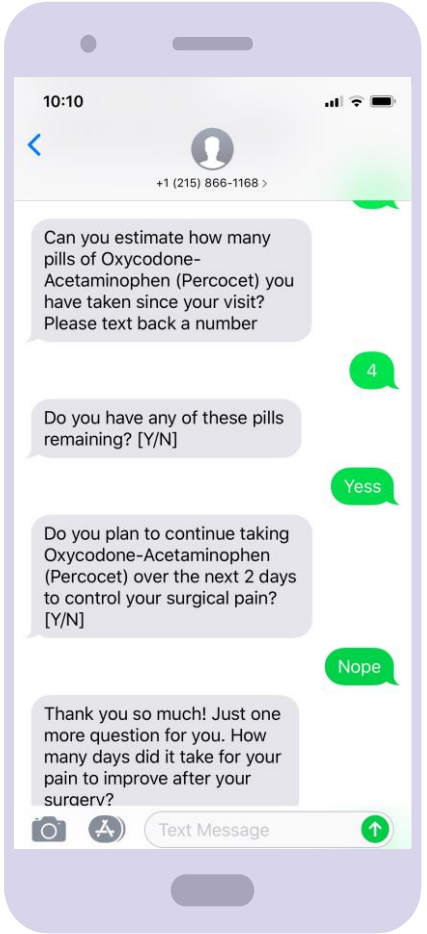
Real-time

Classically Retrospective

Phone call or Survey

Based Methods

Testing the feasibility of gathering acute pain and opioid use through text-messaging.



Approach

1. Design, Test and Implement an Automated Texting Script
   - Manual to Automated
2. In person to Text-Based Consent
   - Offload clinical providers, Opt-Out Messaging
3. Data Collection and Sharing
   - Survey vs. Conversational

Lessons Learned

Iterative Text Messaging Development

Non-opioid vs. Opioid

Lesson: No need to 'prime' patients with questions regarding nonopioid use

Consent

Lesson: Collaborate early with legal and privacy champions to redesign classically in person processes

Health Information

Lesson: Limit PHI and identifying factors.

Clear, Simple & Short

Lesson: Questions should fit text character limits and prompt participants for a simple response (e.g "3" or "yes")

Platform Flexibility

Lesson: There is a need for rapid cycle developments and changes to scripts.

Embedded Links

Lesson: Carriers may block or limit links and thus impact data collection.

Learning at scale: Acute Pain and Opioid Use

FDA Sponsored Research

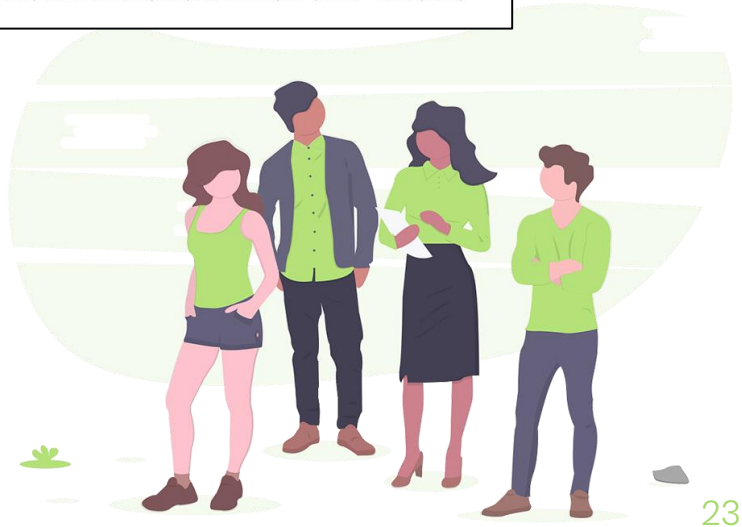
- Multi year project
- Piloted in Orthopedics and Rapidly Scaled
- Post surgical, automated text messaging
- Generate patient-centered data:
  - Pain Intensity
  - Ability to Manage Pain
  - Opioid Use (matched to prescription)
  - Opioid Disposal
- Aggregate Clinician Data
  - Department/Division
  - Procedure Level
  - Prescriber Level

NEJM Catalyst | Innovations in Care Delivery

CASE STUDY

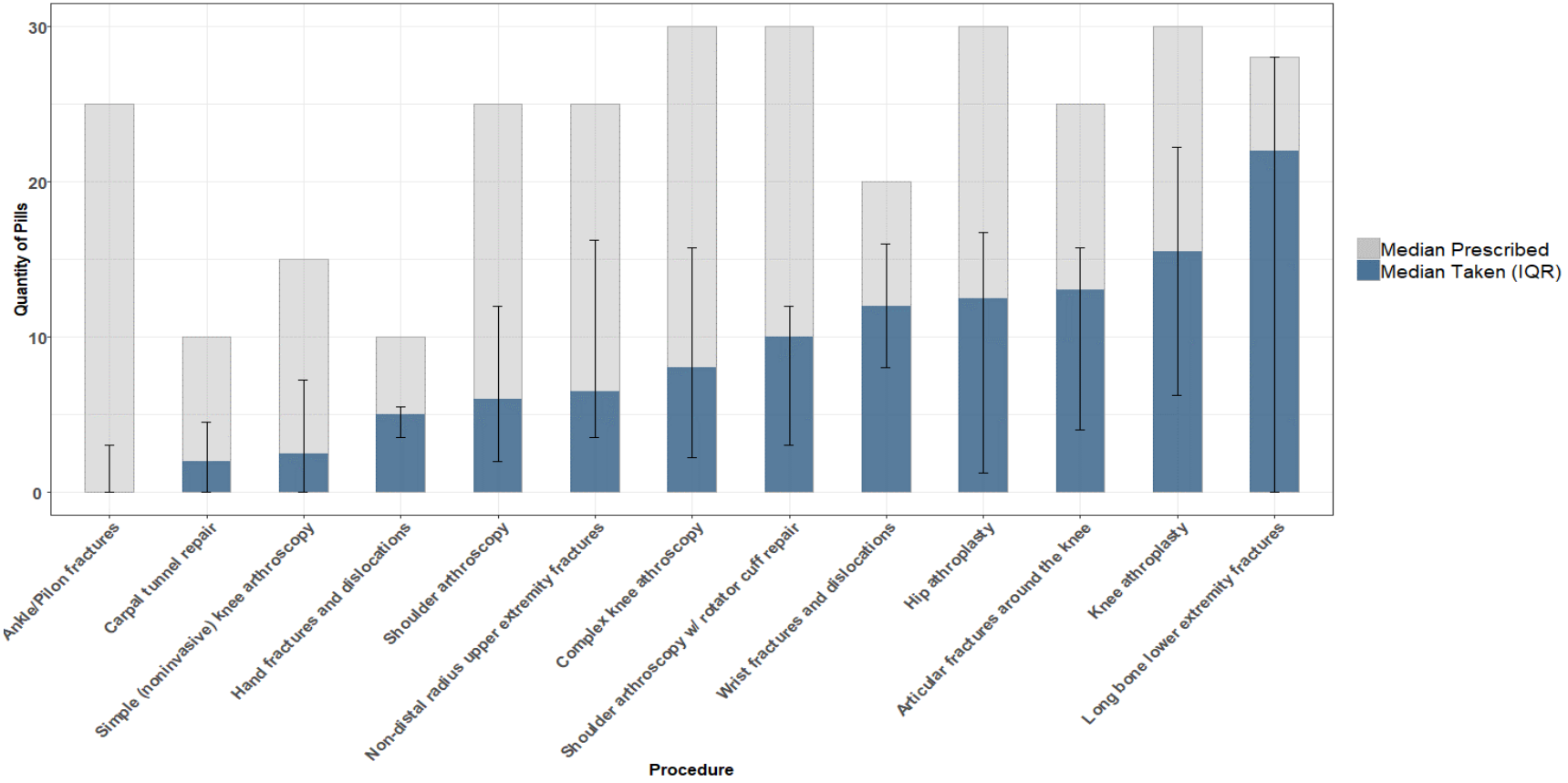
An Automated Text Messaging Program to Inform Postoperative Opioid Prescribing

Anish K. Agarwal, MD, MPH, MS, Zarina S. Ali, MD, MS, Brian Sennett, MD, Ruiying Xiong, MS, Jessica Hemmons, Evan Spencer, Hannah Lacko, MA, Eric Hume, MD, Samir Mehta, MD, M. Kit Delgado, MD, MS



Text-Messaging Data – Patient

Text-Messaging Data – Patient



Scalable & Interdisciplinary Approach

- Continuous process to onboard divisions/departments
- Engagement to date:
  - Opioid Prescribed & texted: 8,763
  - Consented to texting: 54%
  - Filled Opioid Rx: 87%
- Data in Action
  - Identifying patient reported use
  - Informing acute guidelines

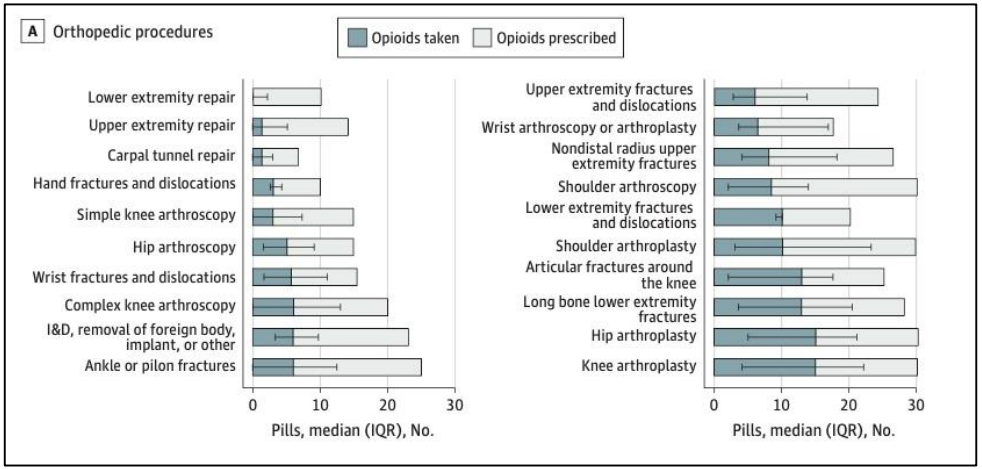
Enrollment By Discharge Service Data currently unavailable for many pre-3/4 discharges	
Cardiac Surgery	445
Cardiovascular Medicine	44
Colorectal Surgery	249
Emergency Medicine	611
Family Medicine	3
Geriatrics	3
GI Surgery	239
Gynecological Onc	1
Infectious Diseases	4
Medicine	81
Neurology	1
Neurosurgery	606
Oncology	9
Orthopedics	5235
Otorhinolaryngology	28
Plastic Surgery	294
Podiatry	5
Pulmonary	1
Surgery - General	323
Surgical Oncology	226
Thoracic Surgery	89
Transplant	42
Trauma Service	256
Urology	1871
Vascular Surgery	101

JAMA Network Open

Original Investigation | Surgery

Patient-Reported Opioid Consumption and Pain Intensity After Common Orthopedic and Urologic Surgical Procedures With Use of an Automated Text Messaging System

Anish K. Agarwal, MD, MPH, MS; Daniel Lee, MD, MS; Zarina Ali, MD, MS; Brian Sennett, MD; Ruiying Xiong, MS; Jessica Hemmons, MS; Evan Spencer, BS; Dina Abdel-Rahman, BS; Rachel Kleinman, MHSA; Hannah Lacko, MA; Annamarie Horan, PhD, MPA; Mary Dooley, PhD; Eric Hume, MD; Samir Mehta, MD; M. Kit Delgado, MD, MS



Pitfalls

Additional ”Work”

Attempting to enroll participants within clinical environments

Complexity in Branching

Introduce friction and lead to fatigue and lower response rates

Embedded Links/Surveys

Can be screened out or never accessed

Privacy and Security

Focus on this up front with key stakeholders

Nudges vs. Overbearing

Balance a gentle reminder and being over bearing

Siloed Research/Efforts

Situational awareness with other trials or programs

Pearls

Keep it Simple

Straightforward and conversational tone

Offload Where Possible

Integration can be helpful to offload participants/clinicians

Opt-out

Allow participants to opt-out up front and provide additional study information

Timing Matters

Think about when to send messages, short and brief reminders as follow up

It's a Hammer

Digital methods are a tool that can facilitate research but often must work with other strategies (e.g. behavioral economics)

Pilot Test Early & Often

Fail fast and be ready to pivot in planning

Future Opportunities

Annals of Internal Medicine ORIGINAL RESEARCH

Comparative Effectiveness of an Automated Text Messaging Service for Monitoring COVID-19 at Home

M. Kit Delgado, MD, MS; Anna U. Morgan, MD, MSc, MSHP; David A. Asch, MD, MBA; Ruiying Xiong, MS; Austin S. Kilaru, MD, MSHP; Kathleen C. Lee, MD; David Do, MD; Ari B. Friedman, MD, PhD; Zachary F. Meisel, MD, MPH, MSHP; Christopher K. Snider, MPH; Doreen Lam, BA; Andrew Parambath, BA; Christian Wood, BA; Chidinma M. Wilson, BA, BS; Michael Perez, BS, BA; Deena L. Chisholm, MPH; Sheila Kelly, MPH; Christina J. O'Malley, MHA; Nancy Mannion, DNP, RN, CEN; Ann Marie Huffenberger, DBA, RN, NEA-BC; Susan McGinley, CRNP; Mohan Balachandran, MA, MS; Neda Khan, BS; Nandita Mitra, PhD; and Krisda H. Chaiyachati, MD, MPH, MSHP

Background: Although most patients with SARS-CoV-2 infection can be safely managed at home, the need for hospitalization can arise suddenly.

Objective: To determine whether enrollment in an automated remote monitoring service for community-dwelling adults with COVID-19 at home ("COVID Watch") was associated with improved mortality.

Design: Retrospective cohort analysis.

Setting: Mid-Atlantic academic health system in the United States.

Participants: Outpatients who tested positive for SARS-CoV-2 between 23 March and 30 November 2020.

Intervention: The COVID Watch service consists of twice-daily, automated text message check-ins with an option to report worsening symptoms at any time. All escalations were managed 24 hours a day, 7 days a week by dedicated telemedicine clinicians.

Measurements: Thirty- and 60-day outcomes of patients enrolled in COVID Watch were compared with those of patients who were eligible to enroll but received usual care. The primary outcome was death at 30 days. Secondary outcomes included emergency department (ED) visits and hospitalizations. Treatment effects were estimated with propensity score-weighted risk adjustment models.

Results: A total of 3488 patients enrolled in COVID Watch and 4377 usual care control participants were compared with propensity score weighted models. At 30 days, COVID Watch patients had an odds ratio for death of 0.32 (95% CI, 0.12 to 0.72), with 1.8 fewer deaths per 1000 patients (CI, 0.5 to 3.1) (P = 0.005); at 60 days, the difference was 2.5 fewer deaths per 1000 patients (CI, 0.9 to 4.0) (P = 0.002). Patients in COVID Watch had more telemedicine encounters, ED visits, and hospitalizations and presented to the ED sooner (mean, 1.9 days sooner [CI, 0.9 to 2.9 days]; all P < 0.001).

Limitation: Observational study with the potential for unobserved confounding.

Conclusion: Enrollment of outpatients with COVID-19 in an automated remote monitoring service was associated with reduced mortality, potentially explained by more frequent telemedicine encounters and more frequent and earlier presentation to the ED.

Primary Funding Source: Patient-Centered Outcomes Research Institute.

Ann Intern Med. doi:10.7326/M21-2019 **Annals.org**
For author, article, and disclosure information, see end of text.
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Published on 4.8.2020 in Vol 8, No 8 (2020): August

Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/preprint/17281, first published December 02, 2019.

Prescribing Behavior Change: Opportunities and Challenges for Clinicians to Embrace Digital and Mobile Health

Anish Agarwal [1, 2, 3, 4]; Mitesh Patel [1, 3, 4, 5, 6]

Thank You

Questions, Thoughts, or Comments?

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